

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns

#### Protocol summary

##### Study aim

Determination of the effect of aromatic massage with aromatic oil of Lavender and Chamomile on reducing anxiety and improving sleep quality in patients with burns

##### Design

Randomized, Semi-experimental study with control group, with parallel groups,

##### Settings and conduct

On Iranian adult patients with burns admitted to the wards of women and men, the burn medical training center of Shahid Motahari Hospital affiliated to the University of Iran

##### Participants/Inclusion and exclusion criteria

Entry requirements Age over 18 years Awareness of time and place Being able to speak and understand Persian language Percentage of burns between 10-45% recorded in the case Skin healthy Skin or back areas Lack of septicemia symptoms with regard to file information It's been 72 hours since burn Lack of physical disability Degree 2 and 3 burns recorded in the case The absence of mental disorder in the past and past recorded in the case No history of asthma and allergies to plants No history of blood pressure and migraine recorded in the file Absence of self-immolation Lack of pregnancy ;Conditions for not admitting to study Sepsis Removal of the skin of healthy legs or back Sensitivity to massage oils

##### Intervention groups

The control group is under the daily care of the department Massage group with aromatic oils, in addition to daily care of the department, is under aromatherapy massage with aromatic oils of lavender and chamomile The placebo group, in addition to day care, undergoes massage with baby oil

##### Main outcome variables

The effectiveness of the aromatic herbal remedy with aromatic oil of lavender and chamomile reduces anxiety and improves the quality of sleep in patients with burns,

potentially reducing the use of anti-anxiety and hypnotic drugs and this method is a complementary non-pharmacological method for patients. Burn should be recommended.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180120038444N1**

Registration date: **2018-01-27, 1396/11/07**

Registration timing: **prospective**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

##### Registration date

2018-01-27, 1396/11/07

##### Registrant information

##### Name

Farzaneh Ameri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4365 1000

##### Email address

ameri.f@tak.iuums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-10, 1396/12/19

##### Expected recruitment end date

2018-07-10, 1397/04/19

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns

**Public title**

Effect of aromatic massage of lavender and chamomile on anxiety and sleep quality of patients with burns

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18 years Awareness of time and place Ability to speak and understand Persian language Percentage of burns between 10-45% recorded in the file Skin healthy areas of the leg or back Lack of septicemia symptoms with regard to file information 72 hours after burn Lack of physical disability Degree 2 and 3 burns recorded in the case Lack of mental disorder present and past recorded in the case No history of asthma and allergies to plants No history of blood pressure and migraine recorded in the file Absence of self-immolation Lack of pregnancy

**Exclusion criteria:**

The sample's reluctance to continue cooperation Sepsis in the study Removal of the skin in healthy areas of the leg or back during the intervention Sensitivity to massage oils used during the study Patient's death

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization with 4-card blocking

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

14665-354

**Approval date**

2017-12-09, 1396/09/18

**Ethics committee reference number**

1396.9413686003

**Health conditions studied****1****Description of health condition studied**

Burn

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

"The effect of aromatic massage with aromatic oil of lavender and chamomile on reducing anxiety and improving the quality of sleep in patients with burns", the primary outcome is the anxiety score in the Spielberger questionnaire and Pittsburgh Sleep Quality Score.

**Timepoint**

Anxiety and quality of sleep are performed at the beginning of the study (before the intervention) and three days later (end of the intervention).

**Method of measurement**

spielberger's anxiety scale, Pittsburgh Sleep Quality scale

**Secondary outcomes****1****Description**

Heart rate and respiratory rate

**Timepoint**

Measurement of respiratory rate and heart rate in the first day (before and after intervention), second (before and after intervention) and third (before and after intervention)

**Method of measurement**

Heart rate with digital pulse oximeter and manual breathing rate with clock aid

## Intervention groups

1

### Description

Intervention group: Intervention group: Under massage with aromatic chamomile and lavender oil (2 drops of pure lavender essential oil and 2 drops of pure chamomile essential oil, prepared from yellow firm, diluted in 30 cc of base oil of grape seed) on areas with healthy skin (legs Foot, back), 10 to 15 cc for 20 minutes, control group: day care group, placebo group: under baby massage with healthy skin (legs, back), 10 to 15 centimeters C, for 20 minutes

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Motahari Hospital in Tehran

#### Full name of responsible person

Mostafa Deh Madhaye

#### Street address

Tehran Province, Tehran, District 3, Vanak, Rashid Yasemi St

#### City

Tehran

#### Province

Tehran

#### Postal code

1454638797

#### Phone

+98 21 8877 0031

#### Email

hospital.motahari@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Deputy Research and Technology

#### Street address

Iran University of Medical Sciences, Hemmat Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1449614535

#### Phone

+98 21 8670 1021

#### Email

research@iums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Farzaneh Ameri

#### Position

Master of Science nursing

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

School of Nursing and Midwifery ,Rashid Yasemi St, Tehran

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Ameri.f@tak.iums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Farzaneh Ameri

#### Position

master of science nursing

#### Latest degree

Bachelor

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Ameri  
**Position**  
Master of science nursing  
**Latest degree**  
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**Other areas of specialty/work**  
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**Email**  
Ameri.f@tak.iums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Total non-Identifiable Data, the Potential of the People  
Sharing

### When the data will become available and for how long

Start Access 2018/5

### To whom data/document is available

Professors and Students

### Under which criteria data/document could be used

-

### From where data/document is obtainable

ameri.f@tak.iums.ac.ir

### What processes are involved for a request to access data/document

Request Via E-mail and Respond by Email Within one  
Week To Do

### Comments